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Attorney Docket No. 5405.225

Application Serial No.: 09/830,045

Page 4**REMARKS**

Claims 1-6 and 8-10 are pending in this application. Claims 8 and 9 are canceled herein without prejudice. Claims 1-5 and 10 are amended herein for clarity to more particularly define the invention. Support for these amendments is found in the language of the original claims and throughout the specification. No new matter is added by these amendments and their entry and allowance are respectfully requested. In light of these amendments and the following remarks, applicants respectfully request reconsideration of this application and allowance of the pending claims to issue.

Rejection under 35 U.S.C. § 112, first paragraph

The Office Action states that claims 1-6 and 8-10 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement.

Claim 1 as presented herein recites a method of identifying a human subject having an increased risk of developing colon cancer, comprising detecting upregulation of the *CLN3* gene in said subject, wherein upregulation of the *CLN3* gene in said subject identifies the subject as having an increased risk of developing colon cancer. Pending claims 2-6 and 8-10 all depend from claim 1.

The methods of claim 1 and of claims dependent therefrom are adequately enabled by the teachings of the instant specification. In particular, claim 1 recites a method for the identification of a human subject, having an increased risk of developing colon cancer, on the basis of detection of upregulation of the *CLN3* gene present in the human subject. The claim does not recite a method for diagnosis or prognosis of a subject; claim 1 only recites a method whereby the subject is identified as having an increased risk of this particular cancer. The detection of upregulation of the *CLN3* gene in a subject is carried out according to methods well known in the art and would be well recognized by one of ordinary skill in the art not to require undue experimentation. The method of claim 1 is enabled by data provided in the specification in

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Example 2 (pages 25-28) demonstrating the detection, by the inventors, of the upregulation of *CLN3* in three separate colon cancer cell lines. Applicants further established a correlation between upregulation of the *CLN3* gene and colon cancer by demonstrating significantly increased *CLN3* mRNA levels in 8 of 10 solid tumors as compared with corresponding normal colon tissue, as set forth in the enclosed Declaration under 37 C.F.R. § 1.132 of Dr. Rose-Mary Boustany. As described in Dr. Boustany's Declaration, these findings clearly enable a method of identifying a human subject as having an increased risk of developing colon cancer by detecting upregulation of the *CLN3* gene in the human subject.

For these reasons, the invention as claimed herein would not require undue experimentation and is adequately enabled pursuant to 35 U.S.C. § 112, first paragraph. Thus, this rejection has been overcome and applicants respectfully request its withdrawal.

In the previous Amendment filed on November 23, 2005, along with the filing of a Request for Continued Examination, Applicants specifically requested the opportunity to discuss this application with Examiner Goldberg and her Supervisory Examiner, Gary Jones, over the telephone before any further official actions were issued for this application, pursuant to MPEP § 713.02 and MPEP § 706.07(b). However, Applicants received the current Office Action with no acknowledgement by the Examiner of their request. Applicants reiterate this request to conduct a telephone interview with the Examiner and her supervisor before any further Office Actions are issued.

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No fee is believed due with this response. However, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



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CERTIFICATE OF FACSIMILE TRANSMISSION

Date of Deposit: March 27, 2006

I hereby certify that this correspondence is being facsimile transmitted to the U.S. Patent and Trademark Office on the date indicated above via facsimile number 571-273-8300 and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


Tracy Wallace